Acme Filter Mask Inc.
No.57, Hu Shan Road, Yingge District, New Taipei City, 23941,Taiwan, R.O.C.

" 510(k) SUMMARY "

MAY 2 0 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is : K123115

Submitter's Name: ***Acme Filter Mask Inc.***
No.57, Hu Shan Road, Yingge District, New Taipei City, 23941,Taiwan, R.O.C.

Date summary prepared: September 23, 2012

Device Name:

- Classification name: *Mask, Surgical*
- Classification number: *FXX, Class II*
- *Regulation Number*: *878.4040*
- Proprietary name: *Surgical Face Mask with Ear-Loop*

  Product model: *YN-501AB, YN-501AW, YN-501AG for Blue, White, Green*

  One size for different colors (Blue, White, Green)
- Common name of device: *Surgical Face Mask, Disposable*
- Predicate Device: *Surgical Face Mask, Type: Tie-on, Ear-loop, K063043*
- Official Correspondent: *Dr. Jen, Ke-Min*

  E-mail: ceirs.jen@msa.hint.net (Tel) +886-3-5208829; (Fax) +886-3-5209783

Description of the device:

Acme Filter Mask Inc. Surgical Face Mask with Ear-Loop is flat pleated 3-ply (at least) masks with an inner and outer layer (spunbonded polypropylene) that sandwich a melt blown polypropylene filter material, also with elastic loops. The nosepiece for all Acme Filter Mask Inc. Surgical Face Masks with Ear-Loop are malleable aluminum wire. All the materials used in the construction of the Acme Filter Mask Inc. Surgical Face Masks with Ear-Loop are being used in currently marked devices.

Labels/Labeling:

This device will be marked to medical device suppliers, Dentist and Doctor Officers, clinics, Emergency Response Professionals, Hospitals and other healthcare professional for the Intended Use purpose below:

Acme Filter Mask Inc.
No.57, Hu Shan Road, Yingge District, New Taipei City, 23941,Taiwan, R.O.C.

Intended Use:

Surgical Face Mask is Device that is intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operation room personnel from transfer of microorganisms, body fluids and particulate material.

Comparison to Predicate Devices:

Acme Filter Mask Inc. Surgical Face Mask with Ear-Loop is substantially equivalent for the safety and effectiveness to the Modern Healthcare Corp. Surgical Face Mask, type: Tie-on and Ear-loop:

Item	Modern Healthcare Corp. Surgical Face Mask (K063043)	ACME Filter Mask Inc. Surgical Face Mask (K123115)
Similarity:		
Fluid Resistance	Fluid Resistance	Fluid Resistance
Flammability Class	Class I (No Flame Spread)	Class I (No Flame Spread)
Regulatory Class	Class II (ASTM2100-04 Low Barrier)	Class II
BFE(%)	Higher than 99%	Higher than 99.9%
Difference:		
Type	Tie-on and Ear-loop (Green, White, Blue, Pink)	Ear-Loop (Green, White, Blue)
Delta-P	Average 2.6	Average 3.33 (mmH_2O/cm^2) for Air Exchange Pressure
Particulate Filtration Efficiency Performance (%)	Average 96.8% at 0.1 micron	Average 94.79% for Solid Aerosol Filtration Efficiency More than 99.5% for Viral Filtration Efficiency

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

I. Fluid Resistance (ASTM F1862-05): Synthetic Blood Penetration Resistance Test
II. Filtration Efficiency: Bacterial Filtration Efficiency (BFE) Test (ASTM F2101-01) and Particulate Filtration Efficiency (latex Particle challenge) (ASTM F1215)
III. Differential Pressure (Delta-P) Test (MIL M 36954 C)
IV. Flammability Test (16CFR 1610)
V. Biocompatibility per ISO 10993-5 /-10

It was our conclusion that performance testing met all relevant requirements of the aforementioned test standard.

Discussion of Clinical Tests Performed:

Not Applicable

Conclusions:

Acme Filter Mask Inc. Surgical Face Mask with Ear-Loop has the same intended use and technological characteristics as the predicated devices Modern Healthcare Corp., Surgical Face Mask, type: Tie-on and Ear-loop (K063043). Especially, the predicate device's types are Tie-on and Ear-loop; and the subject device just for Ear-loop. Besides, the bench testing contained in this submission supplied demonstrates that the technological characteristics do not raise any new question of safety or effectiveness.

Thus the new device is substantially equivalent to the predicate devices.

7. COMPARISON INFORMATION

We place the 510K information for the predicate device thereafter this section.

Comparison to Predicate Devices:

Acme Filter Mask Inc. Surgical Face Mask with Ear-Loop is substantially equivalent for the safety and effectiveness to the Modern Healthcare Corp. Surgical Face Mask, type: Tie-on and Ear-loop:

Item	Modern Healthcare Corp. Surgical Face Mask (K063043)	ACME Filter Mask Inc. Surgical Face Mask (K123115)
Similarity:		
Fluid Resistance	Fluid Resistance	Fluid Resistance
Flammability Class	Class I (No Flame Spread)	Class I (No Flame Spread)
Regulatory Class	Class II (ASTM2100-04 Low Barrier)	Class II
BFE(%)	Higher than 99%	Higher than 99.9%
Difference:		
Type	Tie-on and Ear-loop (Green, White, Blue, Pink)	Ear-Loop (Green, White, Blue)
Delta-P	Average 2.6	Average 3.33 (mmH_2O/cm^2) for Air Exchange Pressure
Particulate Filtration Efficiency Performance (%)	Average 96.8% at 0.1 micron	Average 94.79% for Solid Aerosol Filtration Efficiency More than 99.5% for Viral Filtration Efficiency

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

I. Fluid Resistance (ASTM F1862-05): Synthetic Blood Penetration Resistance Test

X. Filtration Efficiency: Bacterial Filtration Efficiency (BFE) Test (ASTM F2101-01) and Particulate Filtration Efficiency (latex Particle challenge) (ASTM F1215)

XI. differential Pressure (Delta-P) Test (MIL M 36954 C)

XII. Flammability Test (16CFR 1610)

XIII. Biocompatibility per ISO 10993

It was our conclusion that performance testing met all relevant requirements of the aforementioned test standard.

Acme Filter Mask Inc.
No.57, Hu Shan Road, Yingge District, New Taipei City, 23941,Taiwan, R.O.C.

Discussion of Clinical Tests Performed:

Not Applicable

Conclusions:

Acme Filter Mask Inc. Surgical Face Mask with Ear-Loop has the same intended use and technological characteristics as the predicated devices Modern Healthcare Corp., Surgical Face Mask, type: Tie-on and Ear-loop (K063043). Especially, the predicate device's types are Tie-on and Ear-loop; and the subject device just for Ear-loop. The performance tests for the Delta-P and Particulate Filtration Efficiency Performance also have the similar effectiveness. Besides, the bench testing contained in this submission supplied demonstrates that the technological characteristics do not raise any new question of safety or effectiveness.

Thus the new device is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

May 20, 2013

Dr. Ke-Min Jen
ACME Filter Mask
No. 57 Hu Shan Road
Yingge District,
New Taipei City, Taiwan R.O.C. 23941

Re: K123115
Trade/Device Name: Surgical Face Mask with Ear-Loop Model: YN-501AB, YN-501AW, YN-501AG for Blue, White, Green
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: April 12, 2013
Received: April 17, 2013

Dear Dr. Jen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

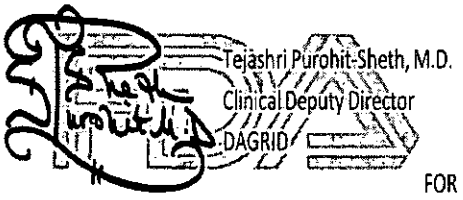
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (K) Number (If Known): K123115

Device Name: *Surgical Face Mask with Ear-Loop*

Model: YN-501AB, YN-501AW, YN-501AG for Blue, White, Green

Indications for Use:

The Surgical Face Mask of different colors (Blue, White, and Green) is a device intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operation room personnel from transfer of bacteria, body fluid and particulate material.

This Surgical Face Mask is non-sterilized and disposable.

Prescription Use _____ AND/OR Over-The-Counter Use √

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Tejashri S. Purohitsheth -S
2013.05.17 13:52:16 -04'00'

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123115